

**Notice of Allowability**

Application No.

10/074,220

Examiner

Sally A. Sakelaris

Applicant(s)

KUMAMOTO ET AL.

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3/28/2005.
2. ☒ The allowed claim(s) is/are 1,4-6,10-12 and 14-17.
3. ☒ The drawings filed on 2/12/2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

JEFFREY FREDMAN  
PRIMARY EXAMINER  
6/10/05

***EXAMINER'S AMENDMENT***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In the claims:

1. Please cancel the presently withdrawn, claim 13.

***THE FOLLOWING IS AN EXAMINER'S STATEMENT OF REASONS FOR  
ALLOWANCE:***

2. The present invention is found to be allowable subject matter as its presentation of a method for predicting irritant potential of a candidate substance comprising detecting an increase in the release of ATP and/or ADP when said candidate substance is cultured with a mammalian keratinocyte represents a contribution over the prior art that teaches only the detection of ATP release in other cell types such as endothelial when such cells are subjected to shear stress and to endotoxins such as lipopolysaccharide (LPS)(Bodin et al.). The prior art also teaches a method that detects a decrease in ATP in a epidermal and dermal sample from a rat in response to a dose of the skin irritant tributyltin(TBT) but does not indicate that the decrease in the tissue is necessarily indicative of an increased release of ATP into the tissue's surrounding medium. It is for example possible that the ATP is being degraded through a different pathway, not necessarily that a decrease in a tissue sample would be indicative of an increase in ATPs being released from the tissue. This possibility is not sufficient to support an inherency rejection since the standard for inherency requires that the result be necessary, not just any of a number of possibilities. In

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this case the result is not necessarily ATP release, such an explanation represents a single possibility.

The closest prior art made of record is as follows:

Bodin et al. (Inflammatory Research 47 (1998) 351-354 teach ATP release in endothelial cells in response to sheer stress and a known toxin.

Middleton, MC. (The Journal of Investigative Dermatology, 79: 163-166, 1982.) teach the detection of decreased ATP in epidermal and dermal samples in rat in response to tributyltin.

It should also be noted that it would not be obvious to combine a method practiced on cell types other than keratinocytes with the present method of detecting ATP release since the specification and prior art do not enable the method where a diverse population of irritants prove reproducible results in the same way as they do in keratinocytes alone.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A. Sakelaris whose telephone number is 571-272-0748. The examiner can normally be reached on M-Fri, 9-6:30 1st Friday off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sally Sakelaris

6/8/2005

  
JEFFREY FREDMAN  
PRIMARY EXAMINER

6/10/05